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December 22, 2005

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Application No. 10/740,694

Filed: December 22, 2003

Title: Method and Compositions for Identifying Anti-HIV

Therapeutic Compounds

Applicants: Murty N. ARIMILLI et al.

Atty. Docket: 18477.031

Sir:

The following documents are forwarded herewith for appropriate action by the U.S. Patent and Trademark Office:

- 1. a Response to Restriction Requirement; and
- 2. a return postcard.

Please stamp the attached postcard with the filing date of these documents and return it to our courier.

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe any fees are due in conjunction with this filing. However, if any fees are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Arnold & Porter LLP Deposit Account No. 50-2387 referencing matter number 18477.031. A duplicate copy of this letter is enclosed.

Respectfully submitted,

David R. Marsh (Reg. No. 41,408)

Lisa A. Adelson (Reg. No. 51,204)

Enclosures



In re Patent Application of:

Murty N. Arimilli et al.

Appl. No.: 10/740,694

Filed: December 22, 2003

For: Method and Compositions for

Identifying Anti-HIV Therapeutic

Compounds

Confirm. No.: 1095

Art Unit: 1648

Examiner: Louise Z. Wang

Atty. Docket: 18477.031

Response to Restriction Requirement

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In response to the Office Action dated November 22, 2005, Applicants submit the following response.

The application presently contains pending claims 1-180. In the Office Action dated November 22, 2005, the Examiner required restriction to one of the following inventions under 35 U.S.C. § 121:

Group I: Claims 1-3, in part, 29-33, 61-65, 92-96, and 122-125, drawn to [the] method for identifying a candidate compound as a suitable pro-drug, comprising contacting the candidate compound with a catalyst having carboxylic ester hydrolase activity to produce a metabolite compound; and identifying the candidate compound as a suitable pro-drug if the metabolite compound has a phosphonic acid group instead of the esterified phosphonate group of the

candidate compound, or a carboxylic acid group instead of the esterified carboxyl group of the candidate compound, classified in class 435, subclass 19, for example.

Group II: Claims 4-8, 34-40, 66-71, and 97-101, drawn to the method of providing a candidate compound by substituting a prototype compound with an esterified phosphonate or carboxyl group, classified in class 435, subclass 135, for example.

Group III: Claims 9-11, 41-43, 72-74, 102-104, and 144-147, in part, drawn to the method of determining the intracellular persistence of the candidate compound and the metabolite compound, classified in class 435, subclass 7.2, for example.

Group IV: Claims 12-14, 44-46, 75-77, 105-107, 179 and 180, drawn to the method of determining the tissue selectivity of the candidate compound and the metabolite compound, classified in class 435, subclass 4, for example.

Group V: Claims 15, 16, 47, 48, 78, 79, 108, 109, 148-151, 156-159, and 144-147, 152-155, and 169-172, in part, drawn to the method of determining the anti-HIV protease activity of the candidate and metabolite compound, classified in class 435, subclass 4, for example.

Group VI: Claims 17-19, 49-51, 80-82, 110-112, 168 and 169, drawn to the method of determining the resistance of HIV to the candidate and metabolite compound, classified in class 435, subclass 4, for example.

Group VII: Claims 20-28, 52-60, 83-91, 113-121, and 173-178, drawn to the method of determining the intracellular residence time of the candidate compound and the metabolite compound, classified in class 435, subclass 7.21, for example.

Group VIII: Claims 126-129, drawn to a candidate compound that is an amino acid phosphonoamidate in which a carboxyl group of the amino acid is esterified, classified in class 435, subclass 135, for example.

Group IX: Claims 130-137, drawn to a candidate compound that is substituted with an amino acid group in which a carboxyl group of the amino acid is esterified, classified in class 435, subclass 135, for example.

Group X: Claims 138-143, drawn to a candidate compound wherein the esterified phosphonate group is mono-substituted with a hydroxyorganic acid linked to the phosphorus atom through an oxygen atom, classified in class 435, subclass 135, for example.

Group XI: Claims 152-155 and 169-172, in part, and 160-163, drawn to the method of determining the inhibition activity against HIV integrase of the candidate and metabolite compound, classified in class 435, subclass 4, for example.

Group XII: Claims 152-155 and 169-172, in part, and 164-167, drawn to the method of determining the inhibition activity against HIV reverse transcriptase of the candidate and metabolite compound, classified in class 435, subclass 4, for example.

Applicants respectfully traverse the restriction requirement, and provisionally elect the claims of Group I, namely, Claims 1-3, in part, 29-33, 61-65, 92-96, and 122-125.

In the Office Action dated November 22, 2005, the Examiner further stated a species election requirement. The Office stated that:

"Should Applicant elect Group I, Application is additionally required to elect an experimental environment as exemplified by claims 29-32." See Office Action mailed November 22, 2005 at page 5.

"Should Applicant elect Group V, Application is additionally required to elect an assay environment as exemplified by claims 23-27." *Id* at page 6.

Applicants respectfully traverse the election requirement, and provisionally elect the experimental environment as exemplified by Claim 31, cell culture.

The Office alleges that Groups "I-VII, XI, and XII are different methods with respect to starting materials, physiological mechanisms, protocol procedures, and end products." Office Action mailed November 22, 2005 at page 5. The Office further alleges that "[b]ecause these inventions are distinct ... restriction for examination purposes as indicated is proper." *Id.*However, without addressing the Office's allegations regarding distinctness, Applicants respectfully direct the attention of the Office to Section 803 of the MPEP, which instructs that, "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." Applicants respectfully submit that the Office has not shown that a search and examination of the entire application would cause any burden, or more particularly a serious burden. Moreover, Applicants respectfully submit that examination of the application would be handled most expeditiously by treating all of the pending claims as a single entity.

Based upon the foregoing, Applicants submit that the restriction requirement is improper and therefore should be withdrawn. To facilitate prosecution, however, Applicants have

provisionally elected, with traverse, Group I, Claims 1-3, in part, 29-33, 61-65, 92-96, and 122-125.

The Office further alleges that "[t]his application contains claims directed to ...

patentably distinct species...." Office Action mailed November 22, 2005 at page 5. The Office requires additional election should Applicants elect Group I or Group V. For example, the Office asserts that Applicant is additionally required to elect an experimental environment, and that these species are distinct because their structures, components, and physiological properties are different. See Office Action mailed November 22, 2005 at pages 5-6. The Office argues that "... it would be burdensome to search these species together." Applicants respectfully disagree.

Applicants submit that examination of the application would be handled most expeditiously by treating the claims of Group I as a single entity.

Based upon the foregoing, Applicants submit that the election requirement is improper and therefore should be withdrawn. To facilitate prosecution, however, Applicants have provisionally elected, with traverse, the experimental environment as exemplified by Claim 31, cell culture.

The Office states that "Applicant is required under 35 U.S.C. §121 to ... list all claims readable thereon." Office Action mailed November 22, 2005 at page 6. Applicants disagree.

Nonetheless, in order to facilitate prosecution, Applicants respectfully submit that at least Claims 1-3, 31-33, 63-65, 94-96, and 124-125 of Group I are readable on a cell culture environment.

Based upon the foregoing, Applicants submit that the restriction and election

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requirements are improper and should be withdrawn. To facilitate prosecution, however,
Applicants have provisionally elected, with traverse, Group I, Claims 1-3, in part, 29-33, 61-65,
92-96, and 122-125. In addition, Applicants have provisionally elected, with traverse, the
experimental environment as exemplified by Claim 31, cell culture.

Should the Examiner have any questions regarding this application, she is encouraged to contact Applicants' undersigned representative at (202) 942-5325. Authorization to charge any official fees associated with this filing is given in the accompanying transmittal letter.

Respectfully submitted,

David R. Marsh (Reg. No. 41,408)

Lisa A. Adelson (Reg. No. 51,204)

DATE: December 22, 2005

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